

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/322,352 05/28/99 PESCHLE

C 9855-26U1

000570 HM22/1004
AKIN GUMP STRAUSS HAUER & FELD LLP
ONE COMMERCE SQUARE
2005 MARKET STREET SUITE 2200
PHILADELPHIA PA 19103

EXAMINER

VANDER VEGT, F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED:

10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|----------------------------------|-------------------------------|
| Application No. 09/322,352 | Applicant(s) Peschle et al |
| Examiner F. Pierre VanderVegt | Group Art Unit 1644 |

- Responsive to communication(s) filed on _____.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 1-70 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) _____ is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims 1-70 are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1644

DETAILED ACTION

This application claims priority to provisional application 60/087,153.

Claims 1-70 are currently pending in this application.

5 **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

10

Election/Restriction

- 15 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- 20 I. Claims 1-11, 18-32, 39-44, 51-53 and 67-69, drawn to a method of isolating human KDR+ hematopoietic stem cells, classified in class 435, subclass 7.21.
- 25 II. Claims 12-17, 33-38, 45-50 and 54-59, drawn to an enriched population of human hematopoietic stem cells, classified in class 435, subclass 372.
- 30 III. Claims 60-61, drawn to a blood substitute, classified in class 435, subclass 2.
- IV. Claims 62-64, drawn to a chimeric non-human animal, classified in class 800, subclass 8.
- V. Claims 65 and 66, drawn to transplanting human hematopoietic stem cells, classified in class 424, subclass 93.7.
- 35 VI. Claim 70, drawn to a method of assaying patient status by detecting KDR+ human hematopoietic stem cells, classified in class 435, subclass 29.
- 35 2. The inventions are distinct, each from the other because of the following reasons:
Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are

Art Unit: 1644

not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of isolating cells for their further use in therapeutic methods in Group I while Group VI is an assay method taking samples from stages of a subject's condition 5 and measuring in vivo cell levels.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cells 10 of Group II can also be obtained in manners other than the method of Group I. The claims are written in a product-by-process manner, but the manner of isolation does not affect the physical characteristics of the cells..

Inventions II and III-V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the 15 product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells can also be stimulated to differentiate in vitro in order to study or repopulate specific progeny lineages.

20 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

25 4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1644

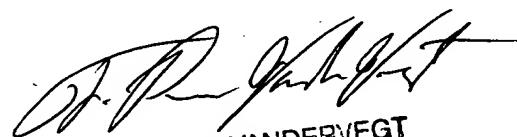
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

- 10 6. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

15 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calendar) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

20
25 F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
October 2, 2000



F. PIERRE VANDERVEGT
PATENT EXAMINER